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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/563.062 PARK ET AL. Office Action Summary Examiner Art Unit ABIGAIL FISHER 1616 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 25 September 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4)\(\times\) Claim(s) 1.3-6.8.10-13.17.18.21.22.24.25.30.31.37 and 45-60 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1, 3-6, 8, 10-13, 17-18, 21-22, 24-25, 30-31, 37 and 45-60 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date

2) Notice of Draftsporson's Patent Drawing Review (FTO-945)

3) Information Disclosure Statement(s) (PTO/SB/08)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date

6) Other:

5) Notice of Informal Patent Application

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DETAILED ACTION

Receipt of Amendments/Remarks filed on September 25 2009 is acknowledged. Claims 2, 7, 9, 14-16, 19-20, 23, 26-29, 32-36 and 38-44 were/stand cancelled. Claims 1, 10-13, 18, 21-22, 24-25, 30-31 and 46 were amended. Claims 48-60 were added. Claims 1, 3-6, 8, 10-13, 17-18, 21-22, 24-25, 30-31, 37 and 45-60 are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1, 3-16, 19-22, 24-36 and 45-47 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **withdrawn** in light of Applicants' amendments filed on 9/25/09.

The rejection of claim 18 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **withdrawn** in light of Applicants' amendments filed on 9/25/09

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The rejection of claim 16 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **moot** in light of the cancellation of claim 16 in the amendments filed on 9/25/09.

The rejection of claim 46 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **withdrawn** in light of Applicants' amendments filed on September 25 2009.

New Rejections Necessitated by the Amendments filed September 25 2009

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-6, 8, 10-13, 17-18, 21-22, 24-25, 30-31, 37 and 45-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 48 claim that a component which is adversely affected by UV light is a light stabilizer. This is confusing as wouldn't a light stabilizer by definition be something that stabilizes a composition to light? Therefore, it is unclear how it is adversely affected by light.

Claim 48 recites that component (b) is a polymer material or molecule. However claims 49 and 50 which depend from claim 48 recite that the composition comprises one or more polymer materials. Therefore, it is unclear if the polymeric materials are in addition to the polymeric material claimed in 48. If not, then it is unclear how the

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composition can comprise one or more as claim 48 specifically recites that the composition comprises a (which means singular) polymeric material.

Claims 3-6, 8, 10-13, 17-18, 21-22, 24-25, 30-31, 37, 45-47 and 51-60 are included in the rejection as they depend on a rejected base claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Applicant Claims
- 2. Determining the scope and contents of the prior art.
- Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1, 10-22, 24, 26-29, 35-37 and 47 under 35 U.S.C. 103(a) as being unpatentable over Mitchnick et al. (US Patent No. 5441726, cited on PTO Form 1449) is **withdrawn** in light of Applicants' amendments filed on September 25 2009.

The rejection of claims 9, 25 and 45-46 under 35 U.S.C. 103(a) as being unpatentable over Mitchnick et al. in view of Knowland et al. (WO 99/60994, cited on PTO Form 1449) is withdrawn in light of Applicants' amendments filed on September 25 2009.

New Rejections Necessitated by the Amendments filed September 25 2009

Claims 1, 3-6, 8, 10-13, 17-18, 21-22, 24-25, 37, 45-48 and 54-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knowland et al. (WO 99/60994, cited on PTO Form 1449) in view of Mitchnick et al. (US Patent No. 5441726, cited on PTO Form 1449).

Applicant Claims

The instant application claims a UV sunscreen composition which comprises: (i) a UV sunscreen agent, a polymer or molecular having ethylenic unsaturation, an amide linkage, an ester linkage, a chlorine atom or a tertiary hydrogen atom or a light

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stabilizer; (ii) a doped titanium dioxide and (iii) an undoped and non-reduced metal oxide selected from titanium dioxide, zinc oxide and mixtures thereof.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Knowland et al. teaches UV screening compositions comprising particles capable of absorbing UV light. It is taught that sunscreens typically contain titanium dioxide to reflect and/or absorb UV light (column 1, lines 11-12). The particle size is generally from 1 to 200 nm (page 3, lines 22-23). The particles may also be titanium or zinc oxide that has been doped with nickel, iron, chromium, aluminum, manganese, among others (page 5, lines 1-7). Example 3 is directed to manganese doped titanium dioxide. It is disclosed that titanium dioxide can be rutile, anatase, or a combination thereof. The table on page 13 discloses the ability of the different forms in oxidative degradation of phenol. Knowland et al. teaches 0.5% manganese has shown to be effective, however as low as 0.05% or as high as 10% may also be used (page 5, lines 17-20). Knowland et al. teaches that the particles may have an inorganic or organic coating (page 6, lines 25-26). Examples of these coating materials include oxides of elements such as aluminum, zirconium or silicon. The particles can be coated with one or more organic material such as polymeric organic silicon compounds (page 6, lines 25-31). Knowland et al. teaches the compositions comprising these particles may additionally contain silicones, other UVA, UVB, or broad-band sunscreen agents, colorants, anionic, cationic, nonionic or amphoteric polymers, metal oxide pigments with a particle size from 100 nm to 20000 nm such as iron oxide, among others (page 7, lines 16-22). Metal oxides are generally taught as titanium dioxide and zinc oxide (page 5, lines 102

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and 29 and claim 5). The metal oxides are present at a concentration of about 0.5 to 10% by weight and such compositions may comprise one or more of the compositions of the invention (page 7, lines 8-11). The compositions can be in the form of lotions gels, creams, powders, aerosols, foams, sprays, etc. (page 7, lines 12-15). Particles of the invention include those which are substantially spherical as well as non-spherical (page 3, lines 29-31). The compositions can be utilized in paints, coatings, and compositions for topical application, for example sunscreens (page 1, lines 5-7).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Knowland et al. does not exemplify a formulation comprising doped titanium dioxide and an UVA, UVB or broadband sunscreen ingredient. Knowland et al. does not teach that the additional metal oxides that can be incorporated are titanium dioxide particles. Knowland et al. does not exemplify coating the titanium dioxide particles with inorganic or organic solvents rendering them water-dispersible or oil-dispersible.

Knowland et al. does not specify a particular UVA, UVB or broadband sunscreen ingredient. However this deficiency is cured by Mitchnick et al.

Mitchnick et al. discloses sunscreen lotions containing water, emulsifier, zinc and/or titanium oxides and a UVB absorber (column 11, lines 25-26). Exemplified UVB absorber is octyl methoxycinnamate (column 12). Doped zinc oxides are exemplified. The dopants include Bi and aluminum (column 10). The zinc oxide may be surface modified in order to make them more compatible in a given formulation. One example of a surface modification is a silicone-like compound in order to increase the zinc oxides compatibility with oil-based formulations (column 11, lines 17-21).

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Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to utilize UVA, UVB, or broadband sunscreen agents in the formulation of Knowland et al. One of ordinary skill in the art would have been motivated to add any of these ingredients to example 3 because they are taught by Knowland et al. as being suitable ingredients to incorporate into the invention of Knowland et al. Furthermore, the compositions of Knowland et al. are taught as being sunscreen compositions and UVA, UVB or broadband sunscreen agents are ingredients commonly utilized in the art for these types of compositions. As a general principle it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining them flows logically from their having been individually taught in the prior art. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) MPEP 2144.06.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Knowland et al. and Mitchnick et al. and utilize octyl methoxycinnamate as the UVA, UVB or broadband sunscreen agent. It would have been obvious to one of ordinary skill in the art to utilize this sunscreen agent as it is taught by Mitchnick et al. to be suitable in sunscreen formulations comprising doped oxide particles.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Knowland et al. and Mitchnick et al. and utilize non-doped zinc oxide or titanium dioxide. One of ordinary skill in the art would have been motivated to utilize these particles in addition to those already taught by Knowland et al. because Knowland

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et al. teach that additional metal oxides can be incorporated and metal oxides specified include titanium dioxide and zinc oxide. Additionally, they are taught by both Knowland et al and Mitchnick et al. as being typical ingredients utilized in sunscreen formulations and are taught by Mitchnick et al. to be incorporated into sunscreen products comprising doped oxide particles. As a general principle it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining them flows logically from their having been individually taught in the prior art. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) MPEP 2144.06.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Knowland et al. and Mitchnick et al. and utilize particles coated with an inorganic or organic material. One of ordinary skill in the art would have been motivated to coat the particles because Mitchnick et al. discloses that surface modified make them more compatible in a given formulations and Knowland et al. indicates that they can have an inorganic or organic coating. Therefore depending on the desired formulation of the particles to be used, it would have been obvious to one of ordinary skill in the art to coat the particles. These types of coatings would allow for a subset of the particles to oil-soluble, as Mitchnick et al. indicates, and another subset of the particles to be water-soluble, as Knowland et al. indicates. This would allow for the particles to be present in both phases of the composition and subsequently better coverage.

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Regarding the claimed amount of dopant, amount of the doped metal oxide and particle size of the metal oxide, Knowland et al. teach an amount that overlaps that instantly claimed. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. See MPEP 2144.05 [R-5]

Regarding claim 37, the structure of octyl methoxycinnamate is:

Therefore, octyl methoxycinnamate possess both an ethylenically unsaturated portion therefore it is an ethylenically unsaturated compound and possess a tertiary hydrogen and is therefore a compound possessing a labile hydrogen atom.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

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Response to Arguments

Applicant's arguments with respect to claim 1, 3-6, 8, 10-13, 15-18, 21-22, 24-25, 30-37 and 45-60 have been considered but are moot in view of the new ground(s) of rejection.

Claims 1, 3, 8, 11-13, 17-18, 21-22, 24, 25, 45-48, 54-56 and 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurz et al. (US Patent No. 6436374, cited on PTO Form 1449).

Applicant Claims

The instant application claims a UV sunscreen composition which comprises: (i) a UV sunscreen agent, a polymer or molecular having ethylenic unsaturation, an amide linkage, an ester linkage, a chlorine atom or a tertiary hydrogen atom or a light stabilizer; (ii) a doped titanium dioxide and (iii) an undoped an non-reduced metal oxide selected from titanium dioxide, zinc oxide and mixtures thereof.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01) Kurz et al. is directed to a light-stable cosmetic formulation containing butvl

methoxydibenzoylmethane and doped titanium dioxide. Specifically claimed a process of improving the photostability of the organic sunscreen agent butyl-methoxydibenzoylmethane in a cosmetic composition comprising insoluble inorganic particles with are titanium dioxide particles doped with cerium or iron ions (claim 1). It is taught that many light protection filters are sensitive substances and have low stability

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towards the ultraviolet rays; they break down at a greater or less rate. This results in problems with the shelf life and effectiveness of the corresponding cosmetic formulations (column 1, lines 26-35). Kurz et al. found that the photostability of butyl methoxydibenzovlmethane (BMDM) is increased if insoluble inorganic particles which have good absorption the UVA region are added (column 2, lines 1-5). It is taught that the effectiveness of the inorganic UVA filters is to be attributed to the fact that being insoluble substances they cannot penetrate the skin and as a result remain in a layer on the skin. BMDB, being an organic molecule diffuses into the uppermost layers of the horny skin mean that once applied the formulation is a two-layer system with the lower layer, the BMDM, is reached only by relatively small amounts of energy resulting in reduced degradation of the organic light protection filter (column 2, lines 7-17). The particles taught include microfine titanium dioxide in a particle size preferably in the range of 10 nm to 100 μm (column 2, lines 25-31). Exemplified titanium dioxide is in the rutile form. This form is taught as having very good UVA absorption and is particularly highly suitable for the photo stabilization of BMDM (examples and column 2, lines 32-42). The content of the BMDM is from 0.1 to 10% by weight (column 2, lines 55-59). The content of the inorganic particles is from 0.1 to 30% by weight (column 2, lines 60-61). The light protection filter butyl methoxydibenzoylmethane can be on its own or in combination with one or more UVA filters from difference classes of substances which can be present in an amount form 0.01 to 40% by weight (column 2, lines 62-67). The formulation can comprise further cosmetic additives which are customarily used in this type of preparation including thickeners, emollients, surfactants, preservatives, dyes,

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pigments, etc. (column 3, lines 39-46). The forms include creams or milks (column 3, lines 53-54 and examples), gels (column 4, line 2), solids (column 4, line 8) and aerosols (column 4, lines 11). Example 1 comprises Brij 76 and Carbomer 934, which are polymeric compounds.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

While Kurz et al. teach that doped titanium dioxide can be combined with an organic sunscreen agent to form a more photostable composition, Kurz et al. do not exemplify this formulation. While Kurz et al. teach that other UV filters can be included as well teach utilizing undoped titanium dioxide particles, Kurz et al. do not exemplify formulations comprising doped titanium dioxide, non-doped titanium dioxide and an organic sunscreen agent.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize iron doped titanium dioxide in combination with butyl methoxydibenzoylmethane in the formation of a cosmetic formulation. One of ordinary skill in the art would have been motivated to utilize iron doped titanium dioxide in combination with butyl methoxydibenzoylmethane as this is a specific embodiment claimed by Kurz et al. as well as Kurz et al. teach that iron doped titanium dioxide can be added to cosmetic formations comprising butyl methoxydibenzoylmethane in order to improve the photostability of the cosmetic formulation.

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It would have been obvious to one of ordinary skill in the art to utilize undoped titanium dioxide in combination with butyl methoxydibenzoylmethane and doped titanium dioxide. One of ordinary skill in the art would have been motivated to utilize undoped titanium dioxide as Kurz et al. teach that additional UV filter agents can be utilized and teach that titanium dioxide are organic particles that have good absorption in the UVA range. As a general principle it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining them flows logically from their having been individually taught in the prior art. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) **MPEP** 2144.06.

Regarding the claimed particle size and amount of doped titanium dioxide, Kurz et al. teach an amount that overlaps that instantly claimed. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. See MPEP 2144.05 [R-5]

Regarding the claimed amounts of organic sunscreen agent, Kurz et al. teaches 0.1 to 10% by weight, 0.1 reads on the lower limit in both claimed ranges.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

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Claims 4-6, 10 and 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurz et al. in view of Knowland et al. as evidenced by Nicoll et al. (US Patent No. 5188831)

Applicant Claims

The instant application claims the dopant is manganese. The instant application claims specific amounts of the dopant. The instant application claims the composition comprises a water-dispersible and oil-dispersible titanium dioxide.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Kurz et al. are set forth above. Kurz et al. is directed cosmetic formulations comprising an organic sunscreen agent and doped titanium dioxide which results in a more photostable composition. Specific dopants include iron and cerium.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Kurz et al. does not specify the amount of dopant present with the titanium dioxide. Kurz et al. does not specify the shape of the titanium dioxide. Kurz et al. do not tech utilizing manganese as the dopant. Kurz et al. do not teach utilizing water-dispersible and oil-dispersible titanium dioxide. However, these deficiencies are cured by Knowland et al.

Knowland et al. teaches UV screening compositions comprising particles capable of absorbing UV light. It is taught that sunscreens typically contain titanium dioxide to reflect and/or absorb UV light (column 1, lines 11-12). The particle size is generally from 1 to 200 nm (page 3, lines 22-23). The particles may also be titanium or zinc oxide

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that has been doped with nickel, iron, chromium, aluminum, manganese, among others (page 5, lines 1-7). Example 3 is directed to manganese doped titanium dioxide. It is disclosed that titanium dioxide can be rutile, anatase, or a combination thereof. The table on page 13 discloses the ability of the different forms in oxidative degradation of phenol. Knowland et al. teaches 0.5% manganese has shown to be effective, however as low as 0.05% or as high as 10% may also be used (page 5, lines 17-20). Knowland et al. teaches that the particles may have an inorganic or organic coating. Coatings include oxides such as aluminum, zirconium or silicon. Organic material such as polyols, amines, alkanolamines and polymer organic silicone compounds can be utilized to coat the metal oxides as well (page 6, lines 25-31). Particles of the invention include those which are substantially spherical as well as non-spherical (page 3, lines 29-31).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Kurz et al. and Knowland et al. and utilize manganese as the dopant. One of ordinary skill in the art would have been motivated to utilize manganese as Kurz et al. teach that dopants such as iron and cerium can be utilized and Knowland et al. teach doped titanium dioxide particles for the same purpose as those of Kurz et al. include dopants such as with nickel, iron, chromium, aluminum, and manganese. One of ordinary skill in the art would have been motivated to replace iron with manganese as both are taught by Knowland et al. as functional equivalents.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Kurz et al. and Knowland et al. and utilize

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a dopant in an amount from 0.05% or as high as 10%. One of ordinary skill in the art would have been motivated to utilize this amount of dopant as Kurz et al. and Knowland et al. are both directed to sunscreen formulation comprising doped titanium dioxide and Knowland et al. teach that this amount is a suitable amount of dopant to utilize in combination with metal oxides for sunscreen formulations.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Kurz et al. and Knowland et al. and utilize an organic or inorganic coating on the titanium dioxide in order to affect the dispersibility of the compounds. As evidenced by Nicoll et al. oil dispersible titanium dioxide are titanium dioxide coated with organosilicon compounds where as water dispersible titanium dioxide are those coated with aluminum oxides (column 2, lines 39-50). Therefore, it would have been obvious to one of ordinary skill in the art to coat the titanium dioxide as taught by Knowland et al. in order to manipulate the dispersibility of the titanium dioxide.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima* facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1, 3, 8, 11-13, 22, 24, 30-31, 37, 46, 48-51, 54-55 and 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calvo et al. (US Patent No. 5143723) in view of Kurz et al.

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Applicant Claims

The instant application claims a UV sunscreen composition which comprises: (i) a UV sunscreen agent, a polymer or molecular having ethylenic unsaturation, an amide linkage, an ester linkage, a chlorine atom or a tertiary hydrogen atom or a light stabilizer; (ii) a doped titanium dioxide and (iii) an undoped an non-reduced metal oxide selected from titanium dioxide, zinc oxide and mixtures thereof.

Determination of the Scope and Content of the Prior Art (MPEP \$2141.01)

Calvo et al. is directed to colored cosmetic composition. The compositions, when applied to a person's skin, hair or nails, exhibit exceptional brilliance and clarity of color (abstract). The composition is formed by incorporating a dye into a resin that is transparent to light (claim 1). The resin may be thermoplastic or thermosetting (column 3, lines 13-14). Examples of resins include acrylics (column 3, line 28 and claim 10). Forms of the composition include sticks such as a lipstick (column 5, line 17). When in the form of a stick, waxes, oils, colorants, flavorings or perfumes may be added (column 5, lines 24-37). It is taught that other ultraviolet absorbers such as titanium dioxide may also be included in the composition for the purpose of diminishing the harmful degradative effects of ultraviolet light (column 6, lines 3-9). It is taught that regardless of the form of the product, the composition may also include one or more ingredients are conventionally used in cosmetic compositions such as sunscreens (column 5, lines 56-60).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP \$2141.012)

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Calvo et al. does not teach the addition of doped and non-doped titanium dioxide to the compositions. However, this deficiency is cured by Kurz et al.

Kurz et al. is directed to a light-stable cosmetic formulation containing butyl

methoxydibenzovlmethane and doped titanium dioxide. Specifically claimed a process of improving the photostability of the organic sunscreen agent butylmethoxydibenzoylmethane in a cosmetic composition comprising insoluble inorganic particles with are titanium dioxide particles doped with cerium or iron ions (claim 1). It is taught that many light protection filters are sensitive substances and have low stability towards the ultraviolet rays; they break down at a greater or less rate. This results in problems with the shelf life and effectiveness of the corresponding cosmetic formulations (column 1, lines 26-35). Kurz et al. found that the photostability of butyl methoxydibenzoylmethane (BMDM) is increased if insoluble inorganic particles which have good absorption the UVA region are added (column 2, lines 1-5). It is taught that the effectiveness of the inorganic UVA filters is to be attributed to the fact that being insoluble substances they cannot penetrate the skin and as a result remain in a layer on the skin, BMDB, being an organic molecule diffuses into the uppermost layers of the horny skin mean that once applied the formulation is a two-layer system with the lower layer, the BMDM, is reached only by relatively small amounts of energy resulting in reduced degradation of the organic light protection filter (column 2, lines 7-17). The particles taught include microfine titanium dioxide in a particle size preferably in the range of 10 nm to 100 μm (column 2, lines 25-31). Exemplified titanium dioxide is in the rutile form. This form is taught as having very good UVA absorption and is particularly

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highly suitable for the photo stabilization of BMDM (examples and column 2, lines 32-42). The content of the inorganic particles is from 0.1 to 30% by weight (column 2, lines 60-61). The light protection filter butyl methoxydibenzoylmethane can be on its own or in combination with one or more UVA filters from difference classes of substances which can be present in an amount form 0.01 to 40% by weight (column 2, lines 62-67).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to utilize undoped titanium dioxide in combination with doped titanium dioxide in the composition of Calvo et al. One of ordinary skill in the art would have been motivated to utilize undoped titanium dioxide and doped titanium dioxide as Calvo et al. teach that titanium dioxide can be incorporated for the purpose of diminishing the harmful degradative effects of ultraviolet light as well as additional UV filter agents can be utilized. Kurtz et al. teach that titanium dioxide is organic particles that have good absorption in the UVA range. Therefore, one of ordinary skill in the art would have been motivated to add doped and undoped titanium dioxide for their sunscreen and protective effects. As a general principle it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining them flows logically from their having been individually taught in the prior art. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) MPEP 2144.06.

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Regarding the claimed particle size and amount of doped titanium dioxide, Kurz et al. teach an amount that overlaps that instantly claimed. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. See MPEP 2144.05 [R-5]

Regarding claim 37, polymers taught include acrylics which are ethylenically unsaturated compounds.

Regarding the three dimensional form, a lipstick reads on the claimed threedimensional form.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Modified Rejection Based on amendments in the reply filed on September 25 2009

Claims 1, 3-6, 8, 11-13, 17-18, 21, 30-31, 37, 46, 48-54 and 56-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chopoorian (US Patent No. 3314321, cited on PTO Form 1449) in view of Feist et al. (US PGPUB No. 20020094455, cited in the Office action mailed on 3/27/09) and Smith (US Patent No. 5723271).

Applicant Claims

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The instant application claims a UV sunscreen composition which comprises: (i) a UV sunscreen agent, a polymer or molecular having ethylenic unsaturation, an amide linkage, an ester linkage, a chlorine atom or a tertiary hydrogen atom or a light stabilizer; (ii) a doped titanium dioxide and (iii) an undoped an non-reduced metal oxide selected from titanium dioxide, zinc oxide and mixtures thereof.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Chopogrian is directed to a photochromatic composition comprising inorganic metal oxides suspended in polyester binders. Examples 6 and 7 comprise a polyester resin produced from maleic anhydride, phthalic anhydride, and propylene glycol. It is indicated that these resins contain ethylenic unsaturation (column 5, lines 24-25). Therefore these resins are those ingredients which are adversely affected by UV light in the presence of titanium dioxide and/or zinc oxide. The composition also comprises titanium dioxide that is doped with 0.2% manganese. The doped metal oxide is present in 20% by weight. It is disclosed that these composition have many uses some include temporary photographic proofs (e.g. photographic film) (column 9, lines 21-24). It is disclosed that the polyester resins are thermoplastic and thermosetting (column 1, lines 46-47). It is disclosed that the rutile form of the titanium dioxide is sufficient (column 3, lines 49-50). Additionally, it is indicated that the admixtures contain from about 0.01 to 5 mole% of the doping guest oxide (column 3, lines 53-55). It is also indicated that it is possible to lengthen the life of the composition by incorporating various ultraviolet light absorbers into them. These additives include UV absorbers such as 2-hydroxy benzophenone (column 9, lines 30-40). When these absorbers are added they are

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present in amount up to 20% by weight (column 9, lines 43-45). A third class of photochromic inorganic oxide material is admixtures of titanium dioxide with MoO₃ or WO₃. The titanium dioxide component may either be rutile, anatase, or a mixed phase form. In place of titanium dioxide other metal oxides may be utilized such as zinc oxide (column 4, lines 30-43 and Table 1). It is taught that the compositions of the invention have many uses which include memory devices, devices for temporary data storage, temporary photographic proofs, light storage, optical masks, etc. (column 9, lines 20-26). It is taught that the composition can comprises modifiers, fillers, lubricants, stabilizers, plasticizers, colorants or the like may be included (column 9, lines 3-6).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Chopoorian does not exemplify utilizing titanium dioxide that is doped in different percentages. Chopoorian does not exemplify utilizing UV absorbers in the composition of matter. Chopoorian does not specify the incorporation of titanium dioxide or zinc oxide that is not doped. However, this deficiency is cured by Feist et al.

Feist is directed to a data storage media. It is taught that the data storage media can be produced by first forming a thermoplastic composition and then mixing the various components (paragraph 0035). Once the composition has been produced it can be used to form data storage media or any other desired articles (films, lenses, sheets, etc.) using various molding and processing techniques (paragraph 0037). It is taught that reinforcing agents, fillers and other additives can be used to increase the modulus of the substrate. Fillers and reinforcing agents include titanium dioxide, glass, zinc oxide, zinc sulfide, etc. (paragraph 0034).

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Chopoorian does not specify he particle size of the pigments. However this deficiency is cured by Smith et al.

Smith is directed to photographic elements. It is taught that photographic imagine elements, a solid particle dispersion should have an average particle size of about 0.01 to about 10 microns. Generally, the desired particle sizes can be achieved by milling a solid particle (column 13, lines 51-63).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Chopoorian and Feist and utilize fillers and reinforcing agents such as titanium dioxide and zinc oxide in the composition of Chopoorian. One of ordinary skill in the art would have been motivated to add these fillers and reinforcing agents as Chopoorian teach that these types of agents can be added and Feist et al. teach their use in similar type products which can be added in order to increase the modulus of the substrate. Therefore, it would have been obvious to one of ordinary skill in the art to add titanium dioxide or zinc oxide in order to increase the modulus of the substrate based on the teachings of Feist et al.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize a dopant in an amount from about 0.01 to 5 mole%. One of ordinary skill in the art would have been motivated to select this range because it is disclosed by Chopoorian as being suitable. Therefore one of ordinary skill in the art would have a reasonable expectation that these particles would function effectively with this particular amount of dopant.

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It would have been obvious to one of ordinary skill in the art at the time of the invention to include UV absorbers in the compositions of matter of Chopoorian. One of ordinary skill in the art would have been motivated to include this type of ingredient because Chopoorian indicates that the inclusion of these types of ingredients may lengthen the life of the compositions.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Chopoorian and Smith et al. and utilize particles with an average particle size of about 0.01 to about 10 microns. One of ordinary skill in the art would have been motivated to utilize this particle size range as Chopoorian teaches photographic films and Smith et al. teaches that solid particle dispersions should have this particle size range.

Regarding claim 54, the mixture that is formed from the resin and doped metal oxide, is poured between glass plates (see example 1), therefore it coats the glass plates. This makes the mixture a coating composition and therefore reads on the instant claim.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

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Response to Arguments

Applicants argue that (1) claim 1 is now directed to a UV sunscreen composition suitable for cosmetic use. Chopoorian certainly does not describe a UV sunscreen composition that can be topically applied to a human. Applicants' argue that (2) Chopoorian describes doped metal oxide particles. However, Chopoorian does not disclose the size of the doped metal oxide particles. The Applicants' direct the examiner's attention to Kirk-Othmer which states that for inorganic pigments to be useful in most applications, they must have an average particle size between 0.1 and 10 microns. Therefore one of ordinary skill in the art would understand that the average particle size is greater than the 100 nm upper limit required by the claims.

Applicant's arguments filed September 25 2009 have been fully considered but they are not persuasive.

Regarding applicants' first argument, "for cosmetic use" is an intended use. A recitation of the intended use of the claimed invention, must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Note: MPEP 2111.02 [R-3]. In the instant case, Chopoorian teach that it is possible to lengthen the life of the composition by incorporating various ultraviolet light absorbers into them. These additives include UV absorbers such as 2-hydroxy benzophenone. Therefore, Chopoorian teaches UV sunscreen compositions. Secondly, the components taught in Chopoorian are the same as instantly claimed (resins, doped titanium dioxide,

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sunscreen ingredients). Therefore, there doesn't appear to be any ingredients present that detrimental to humans. Furthermore, there is nothing present in the teachings of Chopoorian that wouldn't suggest that the composition couldn't at least be capable of serving as a nail varnish which is a cosmetic.

Regarding applicants' second argument, the teachings of Kirk-Othmer state that is "most application", this means not all. Second, the lower limit taught reads on the instantly claimed upper limit as 0.1 microns is 100 nm. Secondly, based on the teachings of Smith et al. is it known in the photographic art that solid particles need to be within the range of 0.01 to 10 microns. This amount clearly overlaps that instantly claimed. The size of the solid particles in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize.

Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal size of the titanium dioxide particles in order to best achieve the desired results.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

Modified Rejection Based on amendments in the reply filed on September 25 2009

Double Patenting/Terminal Disclaimer

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Omum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 1, 4-22, 24-29 and 45-47 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10/540649 (US PGPUB No. 2006/0134026) is withdrawn in light of the filing of a Terminal Disclaimer on 9/25/09.

The terminal disclaimer filed on September 25 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application No. 10540649 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The provisional rejection of claims 1, 3-22, 24-36 and 45-47 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8, 10-12, 16-20, 24-32, 34, 36, 50-52, and 54-55 of copending Application No. 10/588071

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(USPGPUB No. 20080031832) in view of Mitchnick et al. is withdrawn in light of the abandonment of the application on 4/14/09.

The provisional rejection of claims 1, 3-22, 24-36 and 45-47 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8, 10-12, 16-20, 24-32, 34, 36, 50-52, and 54-55 of copending Application No. 10/588071 (USPGPUB No. 20080031832) in view of Mitchnick et al. is withdrawn in light of the abandonment of the application on 4/14/09.

The provisional rejection of claims 1, 3-22, 24-25 and 45-47 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 16-17, and 20-21 of copending Application No. 11/207408 (US PGPUB No. 20060039857) in view of Mitchnick et al. is **withdrawn** in light of the abandonment of the application on 10/14/09.

The provisional rejection of claims 1 and 3-22, 24-36 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 16-23, 27, 28, of copending Application No. 10/555570 (US PGPUB No. 20070055000)) is withdrawn in light of the filing of a Terminal Disclaimer on 9/25/09.

The terminal disclaimer filed on September 25 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application No. 10555570 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The rejection of claims 1, 3-6,10-29 and 45 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7-8, and 10

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of U.S. Patent No. 6869596 in view of Mitchnick et al. is withdrawn in light of

Applicants' amendments filed on 9/25/09 limiting the doped particle to be doped titanium

dioxide.

Claims 1, 3-6, 8, 10-13, 17-18, 21-22, 24-25, 45-48 and 56-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 16-17, and 20-21 of copending Application No. 11/054188 (US PGPUB No. 20050169957) in view of Mitchnick et al.

The instant claims are set forth above.

Copending '188 claims a UV screening composition comprising particles. The particles as claimed include a reduced zinc oxide, or zinc oxide and titanium dioxide with a second component. The second components overlap with the dopants of the instant application.

Copending '188 does not claim that sunscreen agent can be added. Copending '188 and '408 does not claim the composition is in the form of a lotion, gel, etc. or that the particles can be coated. Copending '188 does not claim the addition of non-doped titanium dioxide or zinc oxide. However these deficiencies are cured by Mitchnick et al.

Mitchnick et al. indicates that when formulating these particles into a sunscreen composition that other sunscreen components can be added (column 11, lines 54-56). Mitchnick et al. indicates that the preparation of sunscreens in the form of creams and lotions is well known in the art (column 11, lines 49-50). The zinc oxide may be surface

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modified in order to make them more compatible in a given formulation. One example is silicone-like compound in order to increase the zinc oxides compatibility with oil-based formulations (column 11, lines 17-21). Mitchnick et al. teach that generally sunscreen lotions comprise water, emulsifier, zinc and/or titanium oxides and a UVB absorber (column 11, lines 25-26).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of copending '188 and Mitchnick et al. and utilize non-doped titanium dioxide or non-doped zinc oxide. One of ordinary skill in the art would have been motivated to add these metal oxides as they are taught in the art as sunscreen agent typically utilized in sunscreen lotions. Since copending '188 is directed to sunscreen compositions, it would have been obvious to one of ordinary skill in the art to add these metal oxides as they are known to be utilized for the same purpose as the claimed compositions of copending '188.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to formulate the UV screening composition of '188 into a cream or lotion as it was known that these are well known forms of sunscreens. It would have been obvious to one of ordinary skill in the art to utilize coated particles. One of ordinary skill in the art to utilize coated particles. One of ordinary skill in the art would have been motivated to coat the particles because Mitchnick et al. discloses that surface modified make them more compatible in a given formulations. Therefore depending on the desired formulation of the particles will be used, making the particles coated makes them more compatible with the formulations.

This is a <u>provisional</u> obviousness-type double patenting rejection.

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Response to Arguments

Applicants argue that instant claim amendments distinguish the claimed invention over '188.

Applicants' arguments filed September 25 2009 have been fully considered but they are not persuasive.

Specifically claimed particles of copending '188 are titanium dioxide. Therefore, both applications claim the same doped metal oxides.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher Examiner Art Unit 1616

ΑF

/Mina Haghighatian/ Primary Examiner, Art Unit 1616